



## ENVIRONMENTAL PROTECTION AGENCY

[FRL-9327-3]

### Agency Information Collection Activities; Proposed Renewal of Several Currently Approved Collections; Comment Request

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit requests to renew several currently approved Information Collection Request (ICR) to the Office of Management and Budget (OMB). The ICRs are specifically identified in this document by their corresponding titles, EPA ICR numbers, OMB Control numbers, and related docket identification (ID) numbers. Before submitting these ICRs to OMB for review and approval, EPA is soliciting comments on specific aspects of the information collection activities.

**DATES:** Comments must be received on or before *[insert date 60 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit your comments, identified by the docket ID number for the corresponding ICR as identified in this document, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

11P-1575

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

*Instructions:* Direct your comments to the docket ID number for the corresponding ICR as identified in this document. EPA's policy is that all comments received will be included in the docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of

any defects or viruses.

*Docket:* All documents in the docket are listed in the docket index available in <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** For questions regarding EPA Docket ID Number EPA-HQ-OPP-2011-0704: Lily G. Negash, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-8515; fax number: (703) 305-5884; e-mail address: [negash.lily@epa.gov](mailto:negash.lily@epa.gov).

For questions regarding EPA Docket ID Number EPA-HQ-OPP-2011-0902: Ryne Yarger, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 605-1193; fax number: (703) 305-5884; e-mail address: [yarger.ryne@epa.gov](mailto:yarger.ryne@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. What Information is EPA Particularly Interested in?**

Pursuant to section 3506(c)(2)(A) of PRA, EPA specifically solicits comments and information to enable it to:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility.
2. Evaluate the accuracy of the Agency's estimates of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
3. Enhance the quality, utility, and clarity of the information to be collected.
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. In particular, EPA is requesting comments from very small businesses (those that employ less than 25) on examples of specific additional efforts that EPA could make to reduce the paperwork burden for very small businesses affected by this collection.

## **II. What Should I Consider When I Prepare My Comments for EPA?**

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible and provide specific examples.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Offer alternative ways to improve the collection activity.
7. Make sure to submit your comments by the deadline identified under **DATES**.
8. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

### **III. What Do I Need to Know About PRA?**

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information subject to PRA approval unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the Code of Federal Regulations (CFR), after appearing in the preamble of the final rule, are further displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instruments or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in a list at 40 CFR 9.1.

Under PRA, *burden* means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable

instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

#### **IV. Which ICRs Are Being Renewed?**

EPA is planning to submit a number of currently approved ICRs to OMB for review and approval under PRA. In addition to specifically identifying the ICRs by title and corresponding ICR, OMB and docket ID numbers, this unit provides a brief summary of the information collection activity and the Agency's estimated burden. The Supporting Statement for each ICR, a copy of which is available in the corresponding docket, provides a more detailed explanation.

##### *A. Docket ID Number EPA-HQ-OPP-2011-0704*

*Title:* Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects.

*ICR number:* EPA ICR No. 2195.04.

*OMB control number:* OMB Control No. 2070-0169.

*ICR status:* The approval for this ICR is scheduled to expire on August 31, 2012.

*Affected entities:* Entities potentially affected by this ICR include anyone who submits protocols and study reports for environmental research involving human subjects under FIFRA and/or FFDCA. Although EPA has only received such third-party research (i.e., research that is not conducted or supported by EPA) in conjunction with FIFRA from pesticide registrants, it is conceivable that other entities could submit such information in the future. Principal respondents to this ICR are employers of physical, engineering, and life scientists in the fields of research and development.

*Abstract:* The Environmental Protection Agency (EPA or the Agency) is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). In January 2006, EPA issued a final rule to amend the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) at 40 CFR part 26. The information collection activity imposed by this final rule consists of activity-driven reporting and recordkeeping requirements for those who intend to conduct research for submission to EPA under the pesticide laws.

In addition to other protections, if such research involves intentional dosing of human subjects, these individuals (respondents) are required to submit study protocols to EPA and a cognizant local Human Subjects IRB before such research is initiated so that the scientific design and ethical standards that will be employed during the proposed study may be reviewed and approved. Also, respondents are required to submit information about the ethical conduct of completed research that involved human subjects when such research is submitted to EPA.

*Burden statement:* The annual public reporting and recordkeeping burden for this collection of information is estimated to average 598 hours per response for research involving intentional exposure of human subjects, and 12 hours per response for all other submitted research with human subjects. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes

of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. The information requirements identified in the final rule do not duplicate other federal agency information collections.

The ICR, a copy of which is available in the docket, provides a detailed explanation of this estimate, which is only briefly summarized here:

*Estimated total number of potential respondents:* 54.

*Frequency of response:* On occasion.

*Estimated total average number of responses for each respondent:* 1.

*Estimated total annual burden hours:* 20,572 hours.

*Estimated total annual costs:* \$1,712,833. This includes an estimated burden cost of \$1,712,833 and no additional cost for non-burden hour paperwork costs, e.g., investment or maintenance and operational costs.

*Changes in the estimates from the last approval:* The renewal of this ICR will not result in a change in the number of hours in the total estimated respondent burden identified in the currently approved ICR.

*B. Docket ID Number EPA-HQ-OPP-2011-0902*

*Title:* Consumer Research through Focus Groups to Develop Improved Labeling for Pesticide Products

*ICR number:* EPA ICR No. 2367.02.



*OMB control number:* OMB Control No. 2070-0175.

*ICR status:* The approval for this ICR is scheduled to expire on August 31, 2012.

*Affected entities:* Entities potentially affected by this ICR are members of the general public who volunteer to participate in a focus group.

*Abstract:* EPA intends to renew a voluntary information collection for consumer research involving the use of focus groups to test various versions of pesticide product labels and other informational materials intended for the general public. The purpose of this research is to identify the consumer's understanding of the information on a pesticide product label to assure that the consumer can effectively use this information to select the pesticide product most likely to meet their needs and can readily understand label instructions regarding the safe use, handling, and disposal of the product. The collected information will be used to inform the Agency on the need for and nature of potential revisions to EPA guidance and regulations regarding pesticide product labels and to create other user-friendly consumer information materials.

*Burden statement:* The annual public reporting and recordkeeping burden for this collection of information is estimated to average 2 hours per response. The ICR, a copy of which is available in the docket, provides a detailed explanation of this estimate, which is only briefly summarized here:

*Estimated total number of potential respondents:* 300.

*Frequency of response:* On occasion.

*Estimated total average number of responses for each respondent:* 1.

*Estimated total annual burden hours:* 200 hours.

*Estimated total annual costs:* \$6,014. There are no capital expenditures or operational and maintenance costs associated with this collection activity.

*Changes in the estimates from the last approval:* The renewal of this ICR will result in an overall decrease of 181.34 hours in the total estimated respondent burden identified in the currently approved ICR. This decrease reflects EPA's actual costs of conducting a series of 10 focus groups in 2010. This change is an adjustment.

#### **V. What is the Next Step in the Process for these ICRs?**

EPA will consider the comments received and amend the individual ICRs as appropriate. The final ICR packages will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of these ICRs to OMB and the opportunity for the public to submit additional comments for OMB consideration. If you have any questions about any of these ICRs or the approval process in general, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

**List of Subjects**

Environmental protection, Reporting and recordkeeping requirements.

Dated: November 21, 2011.

**Stephen A. Owens,**

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

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